Charles M. Lizza
Phone: (973) 286-6715
Fax: (973) 286-6815
clizza@saul.com
www.saul.com

July 12, 2023

**VIA ECF**

The Honorable Leda D. Wettre, U.S.M.J.
United States District Court
Martin Luther King, Jr. Federal Building
50 Walnut Street, Room 2060
Newark, New Jersey 07102

Re: *Axsome Therapeutics, Inc., et al. v. Teva Pharmaceuticals, Inc.*
Civil Action No. 23-1695 (MEF)(LDW)

Dear Judge Wettre:

This firm, together with Quinn Emanuel Urquhart & Sullivan, LLP, represents Plaintiffs Axsome Therapeutics, Inc. and Antecip Bioventures II LLC in the above-captioned matter.

Enclosed is the parties' Joint Proposed Discovery Plan. We look forward to discussing this and any other issues Your Honor wishes to address at the Initial Scheduling Conference on July 19 at 12:00 p.m.

Thank you for Your Honor's kind attention to this matter.

Respectfully yours,

Charles M. Lizza

Enclosure
cc: All counsel (via email)

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

*Attorneys for Plaintiff*
*Axsome Therapeutics, Inc. and Antecip*
*Bioventures II LLC*

**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

| | |
|---|---|
| **AXSOME THERAPEUTICS, INC., and ANTECIP BIOVENTURES II LLC,**<br><br>**Plaintiffs,**<br><br>**v.**<br><br>**TEVA PHARMACEUTICALS, INC.,**<br><br>**Defendant.** | **Civil Action No. 23-1695 (MEF)(LDW)**<br><br>**JOINT PROPOSED DISCOVERY PLAN**<br><br>**(Filed Electronically)**<br><br>**Initial Scheduling Conference: July 19, 2023 at 12:00 PM ET.** |

Pursuant to Federal Rules of Civil Procedure 16 and 26(f) and Local Civil Rule 26.1(b), Plaintiffs Axsome Therapeutics, Inc. ("Axsome") and Antecip Bioventures II LLC ("Antecip" and, collectively with Axsome, "Plaintiffs") and Defendant Teva Pharmaceuticals, Inc. ("Teva" or "Defendant") have conferred and submit the following Joint Proposed Discovery Plan.

**1. Set forth a factual description of the case. Include the causes of action and affirmative defenses asserted.**

**Joint Response**: This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*., filed by Plaintiffs in response to Teva's submission of Abbreviated New Drug Application ("ANDA") No. 218147 ("Teva's ANDA") with the United States Food and Drug Administration ("FDA").

Axsome sells the prescription pharmaceutical product Auvelity® for the treatment of major depressive disorder ("MDD"). Auvelity® was approved by the FDA on August 18, 2022

and is a combination of two active ingredients, dextromethorphan and bupropion. Teva's ANDA seeks approval from the FDA to commercially market a generic version of Auvelity® before the expiration of United States Patent Nos. 10,780,064 ("the '064 patent"), 10,925,842 ("the '842 patent"), 10,940,124 ("the '124 patent"), and 10,966,942 ("the '942 patent") (collectively, "the patents-in-suit"), all of which Plaintiffs contend are owned by Antecip and exclusively licensed to Axsome. The claims of the patents-in-suit cover, *inter alia*, methods of using dextromethorphan and bupropion to treat MDD. The Orange Book identifies January 7, 2040 as the expiration date for the four patents-in-suit.

Plaintiffs commenced this action following receipt of a notice letter from Teva, dated February 9, 2023, in which Teva stated that it sought to commercially market a generic version of Plaintiffs' Auvelity® drug product before the expiration of the patents-in-suit. Each of the patents-in-suit is listed in the Orange Book for Auvelity®. The Orange Book additionally lists more than 100 other patents that Plaintiffs contend cover Auvelity® and methods of using Auvelity® that are not the subject of Teva's notice letter. The latest expiring of those patents are set to expire on November 5, 2034. As such, the FDA cannot approve Teva's ANDA until at least November 5, 2034.

In this case, Plaintiffs assert that Teva's ANDA submission constitutes infringement of one or more claims of each of the patents-in-suit. Teva denies infringement of the patents-in-suit and alleges that the patents-in-suit are invalid.

**2. Have settlement discussions taken place? Yes _____ No __X___.**

**(a) What was Plaintiff's last demand?**

(1) Monetary demand: $ ____N/A____
(2) Non-monetary demand: ____N/A____

**(b) What was Defendant's last offer?**

(1) Monetary offer: $ ____N/A____
(2) Non-monetary offer: ____N/A____

**3. The parties have ___ have not _X_ exchanged the information required by Fed. R. Civ. P. 26(a)(1). If not, state the reason therefor.**

**Joint Response**: The parties' proposed date for exchange of Rule 26(a)(1) disclosures is attached hereto as Exhibit 1.

**4. Describe any discovery conducted other than the above disclosures.**

**Joint Response**: Defendant produced ANDA No. 218147. Otherwise, no discovery has occurred in this litigation.

**5. Generally, dispositive Motions cannot be filed until the completion of discovery. Describe any Motions any party may seek to make prior to the completion of discovery. Include any jurisdictional Motions and Motions to Amend.**

**Joint Response**: At this time, the parties do not anticipate filing dispositive motions. Should either party wish to file a dispositive motion later in this action, such party shall seek leave from the Court after the close of discovery.

**6. The parties proposed the following:**

**(a) Discovery is needed on the following subjects:**

**Joint Response**: Discovery relating to the claims and defenses in the parties' pleadings, including infringement and validity of the patents-in-suit, as well as various related issues, claims, and affirmative defenses.

**(b) Should discovery be conducted in phases? If so, explain.**

**Joint Response**: Discovery should not be conducted in phases.

**(c) Number of Interrogatories by each party to each other party:**

**Joint Response**: The Federal Rules of Civil Procedure provide a sufficient starting point for the number of interrogatories served by each side. Accordingly, no change to Fed. R. Civ. P. 33(a)(1) regarding interrogatories is requested. Should the need arise, the parties can discuss the possibility of additional interrogatories in the future.

**(d) Number of Depositions to be taken by each party:**

**Joint Response**: The Federal Rules of Civil Procedure provide a sufficient starting point for the number of depositions taken by each side. Accordingly, no change to Fed. R. Civ. P. 30(a)(2)(A)(i) regarding depositions is requested. Should the need arise, the parties can discuss the possibility of additional depositions in the future.

**(e) Plaintiffs' expert report due on _____.**

**Joint Response**: The parties' proposed schedule is attached hereto as Exhibit 1.

**(f) Defendant's expert report due on _____.**

**Joint Response**: The parties' proposed schedule is attached hereto as Exhibit 1.

**(g) Motions to Amend or to Add Parties to be filed by _____.**

**Joint Response**: The parties' proposed schedule is attached hereto as Exhibit 1.

**(h) Dispositive motions to be served within _____ days of completion of discovery.**

**Joint Response**: At this time, the parties do not anticipate filing dispositive motions. Should either party wish to file a dispositive motion later in this action, such party shall seek leave from the Court.

**(i) Factual discovery to be completed by _____.**

**Joint Response**: The parties' proposed schedule is attached hereto as Exhibit 1.

**(j) Expert discovery to be completed by _____.**

**Joint Response**: The parties' proposed schedule is attached hereto as Exhibit 1.

**(k) Set forth any special discovery mechanism or procedure requested, including data preservation orders or protective orders:**

**Joint Response**: A Discovery Confidentiality Order will be required in this action.

**(l) A pretrial conference may take place on _____.**

**Joint Response**: The parties' proposed schedule is attached hereto as Exhibit 1.

**(m) Trial by jury or non-jury Trial?**

**Joint Response**: Non-jury trial.

**(n) Trial date: _____.**

**Joint Response**: The parties' proposed schedule is attached hereto as Exhibit 1.

**7. Do you anticipate any discovery problem(s)? Yes ___ No _X_. If so, explain.**

**8. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problem with out-of-state witnesses or documents, etc.)? Yes _____ No __X____.**

**Plaintiffs' Response**: Should any of the parties' witnesses be located outside of the United States, the parties expect that reasonable efforts will be made to bring those witnesses to the United States for deposition. The parties agree to negotiate in good faith should reasonable accommodations for remote depositions become necessary, and the parties will agree to a protocol for remote depositions in such event.

**9. State whether this case is appropriate for voluntary arbitration (pursuant to L. Civ. R. 201.1 or otherwise), mediation (pursuant to L. Civ. R. 301.1 or otherwise), appointment of a special master or other special procedure. If not, explain why and state whether any such procedure may be appropriate at a later time (i.e., after**

**exchange of pretrial disclosures, after completion of depositions, after disposition of dispositive motions, etc.).**

**Joint Response**: The parties do not believe this case is appropriate for voluntary arbitration, mediation, appointment of a special master, or other special procedure at this time. The case is in its nascent stages, and the parties have different views on the issues in this case. The parties agree to notify the Court if they believe voluntary arbitration or mediation would aid resolution of the action at a later time.

**10. Is this case appropriate for bifurcation? Yes ___ No _X_.**

**11. We do ____ do not _X_ consent to the trial being conducted by a Magistrate Judge.**

**12. Pursuant to Local Patent Rule 2.1(a), the parties report the following from the 26(f) conference:**

**(1) Proposed modification of the obligations or deadlines set forth in these Local Patent Rules to ensure that they are suitable for the circumstances of the particular case (see L. Pat. R. 1.3);**

**Joint Response:** The parties have addressed this issue in the proposed schedule attached hereto as Exhibit 1.

**(2) The scope and timing of any claim construction discovery, including disclosure of and discovery from any expert witness permitted by the Court;**

**Joint Response**: The parties have addressed this issue in the proposed schedule attached hereto as Exhibit 1.

**(3) The format of the Claim Construction Hearing, including whether the Court will hear live testimony, the order of presentation, and the estimated length of the hearing;**

**Joint Response**: The parties will submit this information in the Joint Claim Construction and Prehearing Statement on the date set forth in Exhibit 1.

**(4) How the parties intend to educate the Court on the patent(s) at issue;**

**Joint Response**: The parties intend to educate the Court on the patents at issue through at least submissions to the Court, which may include *Markman* and/or other tutorial(s).

**(5) The need for any discovery confidentiality order and a schedule for presenting certification(s) required by L. Civ. R. 5.3(b)(2).**

**Joint Response**: The parties will submit a proposed discovery confidentiality order by the date set forth in Exhibit 1.

**(6)**

a. **The availability and timing of production of invention records (including inventor laboratory notebooks and analytical test results);**

**Plaintiffs' Response**: Plaintiffs' investigation regarding the availability and timing of production of invention records is ongoing.

b. **The availability and timing of production of ANDA product research and development documents**

**Defendant's Response**: Teva's investigation regarding the availability and timing of production of ANDA product research and development records is ongoing.

c. **The availability and timing of production of ANDA product samples;**

**Defendant's Response**: The parties will discuss production of samples after any such requests have been made by Plaintiffs. Based on its understanding of the parties' claims and defenses at this stage, Teva contends that samples are not relevant or proportional to the issues in dispute.

d. **The date of conception and the date of reduction to practice for each patent asserted in the action, if applicable;**

**Plaintiffs' Response**: Plaintiffs will provide the information required by the Local Patent Rules with their contentions.

e. **Each inventor's availability for deposition in the matter;**

**Plaintiffs' Response**: The parties will discuss inventor depositions after any such requests have been made by Teva.

f. **Availability of foreign witnesses for deposition and foreign documents;**

**Plaintiffs' Response**: Plaintiffs are currently unaware of any foreign Plaintiffs' witnesses or documents.

**Defendant's Response**: Teva is currently unaware of any foreign Teva witnesses. To the extent relevant foreign documents exist, Teva will conduct a reasonable search for and produce such documents in the ordinary course of the litigation.

g. **Whether there is a 30-month stay and if so, when it ends;**

**Joint Response**: The 30-month stay runs until August 10, 2025.

h. **A date for substantial completion of document production and a method for determining compliance;**

**Joint Response**: The parties' proposed schedule is attached hereto as Exhibit 1.

i. **Any other issues or matters that a party believes are time sensitive.**

**Joint Response**: None at this time.

Respectfully submitted,

Dated: July 12, 2023

s/ Charles M. Lizza
Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

OF COUNSEL:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Catherine T. Mattes
Daniel C. Wiesner
Geoff Kirsner
QUINN EMANUEL URQUHART
& SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

*Attorneys for Plaintiffs*
*Axsome Therapeutics, Inc. and*
*Antecip Bioventures II LLC*

s/ Liza M. Walsh
Liza M. Walsh
Christine I. W. Gannon
Patrick S. Salamea
WALSH PIZZI O'REILLY FALANGA LLP
Three Gateway Center
100 Mulberry Street, 15th Floor
Newark, NJ 07102
(973) 757-1100

OF COUNSEL:

Elaine Herrmann Blais
Daryl L. Wiesen
Gerard J. Cedrone
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
Tel.: (617) 570-1000
EBlais@goodwinlaw.com
DWiesen@goodwinlaw.com
GCedrone@goodwinlaw.com

Alexandra D. Valenti
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Tel.: (212) 813-8800
AValenti@goodwinlaw.com

Alison Siedor
GOODWIN PROCTER LLP
1900 N Street NW
Washington, DC 20036
Tel.: (202) 346-4000
ASiedor@goodwinlaw.com

*Attorneys for Defendant*
*Teva Pharmaceuticals, Inc.*

EXHIBIT 1

| Event | Proposed Dates |
|---|---|
| Parties exchange Rule 26(a)(1) disclosures | 7/26/2023 |
| Disclosure of Asserted Claims | 7/26/2023 |
| Parties submit proposed discovery confidentiality order | 8/2/2023 |
| Defendant serves non-infringement and invalidity contentions | 9/15/2023 |
| Plaintiff serves infringement contentions and responses to invalidity contentions | 12/15/2023 |
| Parties exchange proposed claim terms for construction | 1/5/2024 |
| Parties exchange preliminary proposed constructions and identification of intrinsic and extrinsic supporting evidence | 1/26/2024 |
| Parties exchange identification of all intrinsic and extrinsic evidence they intend to rely upon in opposing any proposed claim construction and thereafter meet and confer to narrow issues | 2/9/2024 |
| Joint Claim Construction and Prehearing Statement | 2/28/2024 |
| Parties complete all fact discovery relating to claim construction | 3/29/2024 |
| Opening Markman briefs | 4/12/2024 |
| Parties complete all expert discovery pertaining to Markman issues | 5/10/2024 |
| Responding Markman briefs | 6/11/2024 |
| Parties to submit to the Court a proposed schedule for a Markman hearing | 6/25/2024 |
| Markman hearing | TBD |
| Last day to seek to add new parties or amend pleadings | 8/16/2024 |
| Substantial Completion of Document Production | 8/16/2024 |
| Close of fact discovery | 10/18/2024 |

| Event | Proposed Dates |
|---|---|
| Opening expert reports | 60 days after the close of fact discovery or the Court's Markman opinion, whichever is later |
| Responding expert reports | 60 days after opening expert reports |
| Reply expert reports | 45 days after responding expert reports |
| Close of expert discovery | 60 days after reply expert reports |
| Pretrial Order | TBD |
| Pretrial Conf. | TBD |
| Trial | TBD |